

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENT ABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference FP20940	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/AU2005/000013	International filing date (day/month/year) 7 January 2005	Priority date (day/month/year) 8 January 2004	
International Patent Classification (IPC) or national classification and IPC Int. Cl. <i>A61B 17/68 (2006.01)</i>			
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1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand 15 July 2005	Date of completion of this report 21 April 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer MATTHEW FORWARD Telephone No. (02) 6283 2606

Box No. I Basis of the report

1. With regard to the language, this report is based on:

☒ The international application in the language in which it was filed☐ A translation of the international application into _____, which is the language of a translation furnished for the purposes of:☐ international search (under Rules 12.3(a) and 23.1 (b))☐ publication of the international application (under Rule 12.4(a))☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):☐ the international application as originally filed/furnished☐ the description:

pages as originally filed/furnished

pages* received by this Authority on _____ with the letter of

pages* received by this Authority on _____ with the letter of

☐ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* received by this Authority on _____ with the letter of

pages* received by this Authority on _____ with the letter of

☐ the drawings:

pages as originally filed/furnished

pages* received by this Authority on _____ with the letter of

pages* received by this Authority on _____ with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.3. ☐ The amendments have resulted in the cancellation of:☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 10-17	YES
	Claims 1-9	NO
Inventive step (IS)	Claims 10-17	YES
	Claims 1-9	NO
Industrial applicability (IA)	Claims 1-17	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 EP 0654250 (HOWMEDICA LEININGER GMBH & CO KG)
- D2 WO 2003/007831 (BIONIX IMPLNATS OY)
- D3 WO 2002/009607 (CARON)
- D4 US 4444181 (WEVERS et al)
- D5 EP 0955011 (EOS SARL)
- D6 US 6093188 (MURRAY)
- D7 US 2580821 (NICOLA)
- D8 US 6599290 (BAILEY et al)

The present application defines a bone fixing device "for fixing bone pieces together" and is characterised by there being a number of spaced portions with holes for a fastener to pass through and a pair of "substantially rigid" and connecting members extending between the portions, the connecting members being "deformable without substantially losing rigidity". The device is further defined by an "in use" passage that claims the result of the connecting members extend across fissures between the bone pieces and the connecting members "simultaneously deformed such that the fissures are closed" (claim 1). These features are repeated in method claim 15.

Claim 10 defines the fixing portions and connecting portions as in claim 1, but is characterised by an "in use" section that the fixing portions as concentrically overlapping such that a single fastener can pass through holes in both portions. This arrangement is not suggested by the cited documents D1 to D8. Claims 10 to 14 are considered to be novel and inventive and satisfy the requirements of Articles 33(2) to 33(4).

The matter of claims 1 to 9 must be considered in isolation from the in use (i.e. the result) paragraph of the claims. This paragraph defines how the bone fixing device operates without adding to the technical features of the claim. This paragraph does not define a technical feature of the device, but relates to how the device is manipulated. The cited art does not suggested the procedure defined by this paragraph and when expressed as a method, this paragraph is neither taught nor suggested by documents D1 to D8. Thus claims 15 to 17 are considered to be novel and inventive because they define a method of fixing bone pieces that is not suggested by the cited documents.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

D2 discloses a mesh like deformable implant of plates with holes for fasteners being interconnected means (5). Figures 5 illustrate a range of connecting means (5). It is considered that such means retain their rigidity, i.e. they are able to retain and fix bone pieces, whilst being deformed. The device of D2 is stretched to ensure that it covers the entire area affected area before it is attached using screws or sutures (see page 12). The device of D2 does not compress the bone fragments together; instead it holds them in a desired place whilst healing occurs. It is considered whilst D2 discloses the physical features of the device of claims 1 to 8, it operates in a different manner. As already stated this opinion is restricted to technical features of the claims and as such claims 1 to 8 are considered to lack novelty and also an inventive step in view of D2

D3 provides an osteosynthesis plate in the form of spaced summits (110) with apertures and deformable connecting portions (101, 103). If a pair of the summits with portion (102) is viewed as "a pair of fixing portions" as defined in claim 1, the connecting portions (101, 103) are the "pair of substantially rigid connecting members". It is clear from figure 6 that these connecting portions may be deformed without losing rigidity. This document is considered to disclose the technical features of claims 1 to 6 and 9 and these claims lack novelty and also an inventive step in view of D3.

D7 discloses a plate that attaches a bone and closes a fracture. The plate is deformed before being applied to the bone; the spring action of sections (4) draws the ends of the fractured portions together. It is considered that the bone plate of D7 discloses the features of claims 1 to 4, 6 and 9. These claims lack novelty and also an inventive step in view of D7.

INVENTIVE STEP (IS) Claims: 1 to 9

See under Novelty for discussion of documents D2, D3 and D7.

Document D1 recites a mesh like array of plates with a hole in each plate for a fastener and pre-bent arm between adjacent plates. This bend in the arm allows the plates to move relative to each other without deforming the arm (column 5 lines 12 to 37). Using a pair connecting members as opposed to a single member as in D1 is considered to be an obvious variation and within the ability of the person skilled in the art. Claims 1 to 5 and 7 to 8 lack an inventive step in view of this document.

Documents D4 and D5 are directed to a bone clips with notched interconnecting portions. Claims 7 and 8 lack an inventive step in view of D3 when read in the light of either D4 or D5.

D6 provides an adjustable bone plate made of matching arrays of plates with holes and a series of deformable interconnecting portions. D8 is directed to a spine fixation device having a pair of spaced fixing portions and rigid linking segments that are not deformable. Claims 1 to 17 are novel and inventive in view of these documents.